

### **REMARKS**

Claims 12-23, 25, 26, and 41-42 were rejected. Claim 12, 14, 15, 27, 34, and 42 are amended herein, and claim 13 is canceled herein. Applicants reserve the right to at least pursue amended subject matter, including canceled claims, in subsequent prosecution. No new matter is entered herein.

#### **I. Objection to the Specification**

The specification was objected to for having blanks in place of application numbers. Applicants amend the specification herein to include said numbers. Applicants respectfully request withdrawal of the objection.

#### **II. Issues Under 35 USC §112, Second Paragraph**

Claims 12-23, 25, 26, 41, and 42 were rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner considers claim 12 to be indefinite because the term "Bik polypeptide" is ambiguous. Although Applicants disagree, claim 12 is amended herein solely to further the prosecution of this case to reference SEQ ID NO:3. Applicants submit that the recitation of this sequence information in the claims renders the claims even more definite.

Claim 12 is also rejected as being indefinite for allegedly being incomplete for omitting presumably essential steps. The Examiner considers the claimed method of administering to a cell a mutant Bik polypeptide having an amino acid substitution to lack steps and objectives. Although Applicants disagree, claim 12 is amended herein solely to further the prosecution of this case to address this issue.

Applicants respectfully request withdrawal of the rejection.

#### **III. Issues Under 35 USC §112, First Paragraph-Written Description**

Claims 12-23, 25, 26, 41, and 42 were rejected under 35 USC §112, first paragraph as allegedly failing to comply with the written description requirement.

Applicants respectfully disagree, yet claim 12 is amended herein solely to further the prosecution of this case. Applicants assert that claim 12 as amended herein is definitely enabled. The Examiner notes on pages 4-5 and 8 of the Action that there is description of the mutant sequences, yet claims 13, 14, and 15 directed to specific substitutions were still

rejected under written description. Applicants respectfully disagree, as there is written description of the subject matter of the claims in the specification at least at paragraph [0022], so one of skill in the art would recognize that Applicants had possession of the invention upon filing. Applicants also described methods of inhibiting proliferation of cancer cells in the specification at least at paragraphs [0239]-[0245], [0260]-[0263], and FIGS. 1-5 using the specific claimed Bik mutants, so one of skill in the art would clearly recognize that Applicants had possession of the invention at the time of filing.

Applicants respectfully request withdrawal of the rejection.

#### **IV. Issues Under 35 USC §112, First Paragraph-Enablement**

Claims 12-23, 25, 26, 41, and 42 were rejected under 35 USC §112, first paragraph as allegedly failing to comply with the enablement requirement. The Examiner considers the claims to contain subject matter that was not described in the specification in such a way as to enable a skilled artisan to make and use the invention.

Applicants respectfully disagree yet assert that claim 12 as amended herein is enabled. Applicants assert that claim 12 as amended herein is clearly described. The Examiner notes on pages 4-5 and 8 of the Action that there is description of the mutant sequences. Furthermore, Applicants disclose methods of inhibiting proliferation of cancer cells in the specification at least at paragraphs [0239]-[0245] and FIGS. 1-5 using the specific claimed Bik mutants, so one of skill in the art would clearly recognize that Applicants had enabled the claims directed to the specific Bik mutants. Although the Examiner considers the disclosure to be non-enabling because for any substitution at positions Thr33 and Ser35 one could not predict the function of the mutant. However, Applicants assert that given the limited number of amino acids that could possibly be substituted in at either or both of those sites, the teaching in the specification to make the substitution, and the disclosure concerning how to test the mutants (at least, for example, paragraphs [0239]-[0245] and [0256]-[0259]), it would not be undue experimentation to utilize other Bik mutants.

Applicants respectfully request withdrawal of the rejection.

#### **V. Issues Under 35 USC §102**

Claim 12 is rejected under 35 USC §102 as allegedly being anticipated by Azar et al. (2000). Applicants respectfully disagree.

The Examiner considers a chimeric protein between a Bik polypeptide and gonadotropic releasing hormone to be expected to have an amino acid substitution to join

them. Applicants assert that it is not necessary to lose one or more amino acids from a polypeptide upon linking it to another polypeptide.

Nevertheless, Azar does not teach the particular Bik substitutions of the amended claims, and Applicants respectfully request withdrawal of the rejection.

#### **VI. Conclusion**

If any additional issues remain, please call the undersigned for quick resolution. In view of the above, Applicant believes the pending application is in condition for allowance.


Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. AH-UTSC:791US from which the undersigned is authorized to draw.

Dated:

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Respectfully submitted,

By



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